31/ Reply Brief(3) 6/m 6-10-02

Bet 7-22-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant	:	Schutt et al.	Group Art Unit 1615
Appl. No.	:	09/218,213	
Filed	:	December 22, 1998	
For	:	STABILIZED PREPARATIONS FOR USE IN NEBULIZERS	
Examiner	:	TRAN, S.	

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on

June 10, 2002
(Date)

KF Karen J Moir
~~Kathy Honnold~~
Karen Moir

APPELANT'S REPLY BRIEF UNDER 37 C.F.R. 1.192

Assistant Commissioner for Patents
Washington D.C. 20231

Sir:

Enclosed is Appellant's Reply Brief filed under 37 C.F.R. 1.192 in response to the Examiner's Answer mailed April 10, 2002.

Remarks

The following remarks are offered to help highlight the technology at issue and crystallize the issues for consideration by the Board. As stated in the Summary section of Applicant's Appeal Brief, the present invention relates to methods and systems for administering stabilized dispersions via nebulization to the respiratory tract. Nebulizers work by forming aerosols by converting bulk liquid into small droplets suspended in a breathable gas. The bulk liquid or respiratory dispersion in the case of the present invention is a particulate suspension of perforated microstructures suspended in a fluorochemical suspension medium. Once nebulized, the perforated microstructures are inhaled by a patient during regular respiration without requiring medical supervision or in-patient facilities or care. Unlike prior art formulations, the present

invention employs novel techniques to reduce attractive forces between the dispersed constituents and to reduce density fluctuations in the stabilized dispersion thereby retarding degradation of the preparation by flocculation, sedimentation, or creaming. The stable dispersion of the present invention thereby reduces dosing incongruities thereby facilitating drug delivery.

The rejection maintained by the Examiner seeks to modify a closed-circuit, liquid ventilation apparatus with means for introducing a medicament to the pulmonary system (Faithful et al. 6,041,777) by incorporating teachings of the prior art related to particle morphology and materials useful in administering particulate aerosols to the pulmonary system in inspired gases (Hanes et al. 5,855,931). As set forth by the Examiner, the reason for this modification is to improve the aerosolization of the particles and to reduce particle agglomeration.

There is absolutely no reason for combining the references in the manner proposed by the Examiner. The Faithfull et al. invention is concerned with administering a breathable liquid to the pulmonary system as part of a closed-circuit ventilation therapy. Such therapy is performed in the hospital under medical supervision and care. Medicament may be introduced into the breathable liquid such as with a nebulizer as indicated by the Examiner. However, since any such medicament is introduced into the breathable liquid which is circulated through the lungs with the liquid ventilation apparatus of Faithfull et al., the aerosol characteristics of the medicament does not dictate whether the medicament will successfully navigate the respiratory system and reach the deep lung. Such aerosol characteristics are relevant to inhalation in inspired gases as in Hanes et al. and are not applicable to pulmonary administration of medicament dispersed in a liquid administered to the lung in a closed-circuit, liquid ventilation apparatus. As such, there is absolutely no reason for one of ordinary skill in the art to look to the teachings of Hanes et al. in order to improve aerosol characteristics of the medicament introduced during the liquid ventilation therapy of Faithfull et al.

Conclusions

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of the claims that are presented on appeal. None of the cited references, individually or in combination, describe or suggest the methods and systems of the present invention. Accordingly, Appellants respectfully request that the Board reverse the Examiner's rejection of the claims on appeal.

Respectfully submitted,

Dated: 6/6/02

By: _____

Michael J. Rafa
Registration No. 38,740
Attorney of Record
(650) 631-5053

Please type a plus sign (+) inside this box → [+]

COPY OF PAPERS
ORIGINALLY FILED

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/218,213
Filing Date	December 22, 1998
First Named Inventor	Ernest G. Schutt
Group Art Unit	1615
Examiner Name	S. Tran
Total Number of Pages in This Submission: 11	Attorney Docket Number: 0055.00

ENCLOSURES *(check all that apply)*

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) (please *identify below):*

Appellant's Reply Brief
First Class Mailing Certificate

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Michael J. Rafa; Inhale Therapeutic Systems, Inc.
Signature	Michael J. Rafa
Date	6/10/02

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: 06/10/2002

Typed or printed name	Karen J. Moir		
Signature	Karen J. Moir	Date	6/10/2002